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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,514	06/12/2001	Pamela A. Kramer	ACS 54812 (23471)	5333

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EXAMINER

RAYFORD, SANDRA M

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,514

Applicant(s)

KRAMER, PAMELA A.

Examiner

Sandra M. Nolan-Rayford

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005 and 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28, 32-53 and 58-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58-60 is/are allowed.
- 6) ☒ Claim(s) 25-28, 32-53 and 61-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: CERT. OF MATERIALS FAXED ON 6-30-05

S. M. Nolan-Rayford
7-1-05

5.02

DETAILED ACTION

Claims

1. Claims 25-28, 32-53 and 58-74 are pending.

Comments re: April 11, 2005 Response

2. It is noted that applicant submitted a response on 11 April 2005. That response was not scanned into eDAN/IFW completely.

The examiner requested, and has now received, a faxed copy of pages 15-20 of that response. The faxed papers are enclosed in this action.

Summary of Base Claims

3. The thirteen (13) base claims can be summarized as follows:

Claim 25 covers a method for coating a medical device, which method comprises the step of thermally spray-forming material onto the device to form a coating, with:

a. the type of "thermal spray processing"* used to spray the material selected from the group of:

- cold spray,
- combustion,
- high velocity oxygen fuel, and
- plasma,

b. the coating material selected from the group of:

- metals,
- metal alloys,
- polymers,
- ceramics,
- cermets, and
- metal/polymer composites.

[See note below.]

Important Note: There is no antecedent basis for the phrase “thermal spray processing” in claim 25. However, in the interest of compact prosecution, no new 35 USC 112 rejection is being made in this action.

Claim 43 covers a method of coating an intravascular stent through sold spray thermal processing comprising the steps:

(1) introducing powder particles of metals, metal alloys, and polymers with particles sizes of 1 to 64 microns into a gas selected from the group of: nitrogen, oxygen, air, helium, argon, xenon, and carbon dioxide;

(2) introducing the gas and particles into a supersonic nozzle having an inlet temperature of 380 to 420 C., at an inlet velocity of 300 to 1,200 m/sec and an inlet pressure of 1.5 to 2.5 Mpa to form a high pressure stream;

(3) directing the high pressure stream at a stent placed on a mandrel 8 to 10 mm away from the nozzle, the stent formed from a second material selected from the group consisting of a metal, an alloy and a polymer,

(4) coating the stent with the particles to form a coated stent; and

(5) removing the coated stent from the mandrel.

Claim 44 covers a method of coating a medical device, comprising the steps:

(1) providing a medical device,

(2) providing a coating material containing a metal alloy, and

(3) applying the coating material to the device using a thermal spray process, wherein the type of thermal spray process is selected from the group consisting of cold spray, combustion, high velocity oxygen fuel and plasma.

Claim 58 covers a method of coating a medical device comprising the steps:

(1) providing a medical device,

(2) providing a coating material containing a metal alloy, and

(3) using cold spray thermal processing to apply a variable thickness coating of the metal alloy onto the device.

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Claim 61 covers a method of coating a medical device comprising the steps:

- (1) providing a medical device,
- (2) providing a coating material containing a metal alloy, and
- (3) using a cold spray process to apply a coating of the metal alloy onto the medical device such that the coating has an average grain size of less than 32 microns.

Claim 64 covers a method of coating a medical device comprising the steps:

- (1) forming a metal alloy coating onto a medical device using a thermal spray process selected from the group of: cold spray, combustion, high velocity oxygen fuel, arc and plasma, and

- (2) processing the medical device in a traveling ring furnace where the alloy coating is melted and re-solidified as the ring travels the length of the device.

Claim 65 covers a method of coating a medical device comprising:

- (1) forming a metal alloy coating onto a medical device using a thermal spray process selected from the group consisting of cold spray, combustion, high velocity oxygen fuel, arc and plasma, and

- (2) centerless grinding the outer diameter of the coated device.

Claim 66 covers a method of coating a medical device comprising:

- (1) forming a metal alloy coating onto a medical device using a thermal spray process selected from the group consisting of cold spray, combustion, high velocity oxygen fuel, arc and plasma, and

- (2) drawing the device to as to reduce the thickness of the coating.

Claim 67 covers a method of coating a medical device comprising:

- (1) coating a metal alloy onto an inner diameter of a medical device using a thermal spray process selected from the group of: cold spray, combustion, high velocity oxygen fuel, arc and plasma, and

- (2) boring the inner diameter of the metal alloy coated device to improve dimension and surface roughness.

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Claim 68 covers a method of coating a medical device comprising:

- (1) forming a medical device from a first metal alloy,
- (2) providing a coating material containing a second metal alloy, and
- (3) applying the coating to the medical device using a thermal spray process.

Claim 71 covers a method of coating a medical device comprising:

- (1) providing a medical device,
- (2) providing a 316L stainless steel coating material,
- (3) applying the coating material to the device, via a thermal spray process, to form a coating having an average grain size of less than 32 microns.

Claim 72 covers a method of coating a medical device comprising:

- (1) providing the device,
- (2) providing a coating material containing 316L stainless steel powder, and
- (3) applying the coating material to the medical device using a thermal spray process.

Claim 73 covers a method of coating a medical device comprising:

- (1) providing the device,
- (2) providing a coating material containing a metal alloy, and
- (3) applying the coating material to the medical device using a thermal spray process.

Comment re: the Limitations in Claims 42, 64, 65, 66, and 67

4. The treatment of a substrate after a coating process is deemed intended use and does not serve to distinguish the coated and post-treated substrate from the coated substrate.

Allowable Subject Matter

5. Claims 58-60 are allowed.
6. The prior art of record fails to teach or suggest processes having all of the features recited in these claims.

Comment re: Claim Captioning

7. The captions on the now-pending claims have been corrected.

Rejections Maintained

8. The 35 USC 103 rejection of claims 25-28, 32-53 and 61-74 as unpatentable over Helmus (US 2002/0032477 A1) in view of Kay et al (US 6,502,767) is maintained.
9. The provisional obviousness-type double patenting rejection of claims 25-28, 32-53 and 61-74 as unpatentable over claims 1-20 of Appln. No. 10/283,951, as represented by the claims of 2004/0088038A1) in view of Kay, is maintained.
10. The provisional obviousness-type double patenting rejection of claims 25-28, 32-53 and 61-74 as unpatentable over claims 1-10, 12, 15-21 and 29-31 of Appln. No. 10/331838, is maintained.

Response to Arguments

11. Applicant's arguments filed in the last response have been fully considered but they are not persuasive.

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The arguments presented on pages 12-20 of the last response are not convincing regarding the patentability of claims other than claim 58-60, which recite specific conditions under which the devices are coated.

It is not convincing to say that Kay's coating process cannot be used to coat Helmus' devices because Helmus does not use the claimed processes.

Helmus is not applied as a section 102 reference. Therefore, its failure to teach all of the limitations claimed is not fatal.

After considering all of the arguments made in the last response, the examiner still deems it obvious to use the coating process of Kay to coat the devices of Helmus.

Only claims 58-60, which set out detailed process steps are deemed patentable over the processes suggested by the combined teachings of Helmus and Kay.

The double patenting rejections are maintained because applicant has neither convincingly argued against them nor submitted appropriate disclaimer(s).

Invitation to Telephone Attorney

12. The invitation to call applicant's attorney is noted. However, the written record is appropriate here. An interview would add little to it.

Final Rejection

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action.

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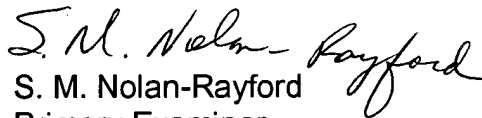
In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication should be addressed to Sandra M. Nolan-Rayford, at telephone number 571/272-1495. She can be reached Monday through Thursday, from 6:30 am to 4:00 pm, ET.

If attempts to reach the examiner are unsuccessful, contact her supervisor, Harold Pyon, at 571/272-1498.

The fax number for patent application documents is 703/872-9306.


S. M. Nolan-Rayford
Primary Examiner
Technology Center 1700

09880514(20050710)